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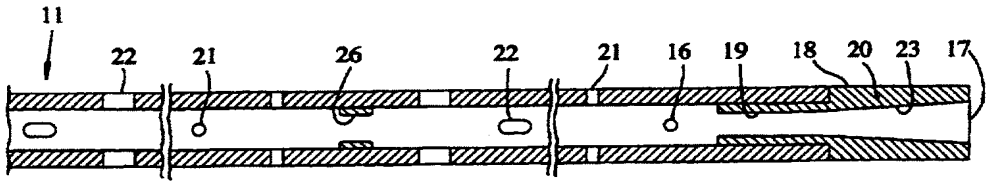

(57) Abstract

Catheter, particularly intended for peritoneal dialysis, comprising a proximal end arranged for connection with a supply and removal arrangement for peritoneal dialysis liquid, and a distal end which is intended to be placed into the peritoneal cavity and provided with a plurality of holes (21, 22) as well as a tip opening (17). The tip is provided with an insert (18) consisting of a restriction (19) and a diffusor (20). The flow which passes out through the tip opening is thereby reduced to 20 % - 25 % of the total flow, while the outflow speed is kept low due to the diffusor. A restriction (26) may be positioned along the portion of the catheter provided with holes at about two-thirds the distance of the vented catheter region measured from the tip opening. The holes in the sidewall of the catheter may comprise different dimensions so that the holes (21) closest to the tip have a small diameter, while the holes (22) near the restriction (26) comprise a larger cross-sectional area. The holes (21) which are closest to the restriction seen from the tip again have the smaller cross-sectional area, followed by holes (22) with larger cross-sectional area. In this way, approximately the same outflow speed is obtained through the different holes as well as through the tip opening.

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TITLE

CATHETER, IN PARTICULAR FOR PERITONEAL DIALYSIS

FIELD OF THE INVENTION

The present invention relates to a catheter, particularly intended for use with peritoneal dialysis. In particular, the invention relates to a peritoneal dialysis catheter suitable for high flow speeds while preventing significant catheter migration. The catheter according to the invention can also be used in other circumstances, such as with the connection to other cavities or vessels in the body, like the stomach, the intestine, the urine bladder, the heart, the brain etc., as well as for connection to blood vessels.

BACKGROUND ART

With peritoneal dialysis, a catheter is used for the supply and removal of dialysis liquid to/from the peritoneal cavity.

A commonly-used catheter is the so-called Tenckhoff-catheter which can be of the straight type or the spiral-shaped type. This catheter consists of a silicon tube, on to which are fastened two dacron pads, to which peritoneal fibres may grow attached, thereby fixing the catheter in position after surgical implantation.

The proximal end of the catheter is connected by means of a connector to a dialysis liquid supply arrangement. The distal end of the catheter is provided with a plurality of holes in its sidewall and generally ends in an opening.

One problem with this catheter is that the holes in the catheter can be blocked during the outward-feed phase, due to the effect of the suction pressure. During the inward-feed phase, too high flows can lead to the catheter moving into the peritoneal cavity. The force which occurs when the fluid flows out causes the tip of the catheter to lash about and to be displaced when the flow is initiated. This catheter migration is one of the reasons for a catheter having to be changed. This movement can also affect the peritoneal membrane's susceptibility to infection.

The liquid also flows out of the catheter through the side holes and, if the flow speed in the sideways direction is too high, discomfort to the patient may result. The flow speed in the forward direction may also cause the patient discomfort.

Catheters for different purposes are described in patent literature. For example, the patent document EP-A1-185 865 relates to an implantable intraperitoneal catheter provided with several spacers in the form of discs which protect the holes in the side of the catheter from becoming blocked by ingrowth. The spacers probably also have a protective effect on the peritoneal membrane which is kept away from the holes where the out-feed flow speed is at its largest. The distal end of the catheter is normally closed but may also be open.

The patent document EP-B1-381 062 describes a catheter for even distribution of therapeutic fluids and comprises a catheter with a plurality of holes along the catheter's sidewall. The diameter of the holes increases towards the distal end of the catheter which is closed. The very small holes are manufactured by laser technology and are rectangular or oblong.

The patent document WO 89/02290 describes a catheter for placement in the ventricular system in the brain. The catheter comprises many small holes which are drilled at an angle with respect to the normal, vis-a-vis the catheter wall.

The patent document US-A-5 057 073 describes a double-lumen catheter for implanting into a patient's vein, for use with hemodialysis treatments. The catheter implanted with the help of a Seldinger thread and the catheter's distal end tip opening is formed with a restriction in order to fit around the Seldinger thread. The wall of the catheter is provided with a plurality of holes for the passage of blood into, and out of, the catheter.

The patent document EP-B1-191 234 discloses a process for providing a medical tube with grooves or slits.

With a straight catheter for peritoneal dialysis having an open distal end, a large part of the total flow, as much as two-thirds, will pass out through the tip opening. High outflow speeds thereby result, which could damage the fibres in the peritoneum. Additionally, the force which acts on the tip of the catheter due to the outflow of fluid in an axial direction becomes excessively high. It is this force which causes the catheter to lash about and be displaced when the flow is initiated. It is desirable to reduce this force, particularly at higher flows.

The problem is greater for shorter catheters with fewer side holes and with straight catheters. With higher mass flows, the proportion which flows out through the tip becomes larger when viewed as a percentage. If the flow is doubled, the outflow speed through the open tip is more than twice as high and the resulting force more than quadruples.

SUMMARY OF THE INVENTION

The object of the present invention is to achieve a catheter, particularly intended for peritoneal dialysis, which can be used for higher flows and have lower flow resistance.

Another object of the present invention is to achieve a catheter wherein the force which affects the tip due to the flow out from an opening in the tip of the catheter, is minimised.

An additional object of the present invention is to achieve a catheter where the outflow through the side holes is as equal as possible.

A simple way of minimising the catheter´s flow resistance is to increase its diameter. This can however give rise to medical problems, like increased susceptibility to infection or a larger risk of leakage.

In order to minimise the flow resistance with an unchanged diameter, it is possible to increase the combined area of the holes in the catheter´s sidewall and tip.

As described above, a large part of the liquid flows through the catheter´s tip opening, which significantly effects the patient and the catheter. By minimising the flow through the tip opening it ought to be possible to divide the out-going flow over a larger area, which would be beneficial for the patient.

According to the present invention, the distal end of the catheter is therefore provided with a restriction, so that a smaller part of the total flow passes out through the tip opening. It is preferred that less than 50% of the total flow passes out through the tip opening and it is particularly preferred that between 20% and 25% of the total flow passes out though the tip opening. A smaller tip opening is also possible so

that more than 5% to 10% of the total flow passes out through this opening.

If the catheter is provided with a restriction so that the flow through the tip opening is 20% to 25% of the total flow, the speed through the opening is however still so great that the problem of the force excerted on the tip of the catheter remains. In order to further reduce this force, without restricting the flow through the tip completely, the tip can be provided with both a restriction which reduces the flow and a conic diffusor which increases the flow diameter and thereby reduces both the speed and the force of the out-going flow.

As explained above, the diffusor's main task is to reduce flow speed rather than to recover pressure. The increase of the diameter for the flow should occur gradually such that the liquid will flow smothly along the diffusors internal surface and therefor without relief. A suitable tip angle (α) of the diffusor is between 3 and 30 degrees, preferably 5 to 15 degrees. Particularly preferred is about 8 to 10 degrees.

According to a preferred embodiment of the invention, the tip can be manufactured as a separate part, or tip insert, which is fixed to the otherwise tube-shaped catheter by means of welding or adhesive. The insert can be manufactured of the same material as the rest of the catheter, such as silicon or polyurethane.

According to a preferred embodiment of the invention, the insert is manufactured of a metal such as titanium or tungsten. In this way, the catheter's tip is somewhat heavier which may be an advantage in certain circumstances. Other metals may also be used if the insert is provided with a coating of a biocompatible material, i.e. the insert is cast in a plastic material. The insert may be cast in the catheter during its manufacture, which thus occurs in one single step.

In order to achieve an even distribution of the outflow through the holes in the catheter's sidewall, these holes are formed having different sizes so that the holes which are nearest to the distal end of the catheter have the smallest diameter. By forming the holes in this way, the first holes, where the flow speed is high and therefore the static pressure is low, have a flow which is the same as that in the smaller holes which are located more distal along the catheter towards the tip where the static pressure is higher and the flow speed is lower. Additionally, only a small part of the area of the first larger holes will be used for effective flow, due to the fact that the fluid in the catheter has a flow component towards the end of the catheter. In order to increase the effective area of the hole, these are, according to the present invention, formed ovally in the longitudinal direction of the catheter.

In order to reduce the flow speed out through the holes, a plurality of holes may be provided. If too many holes are provided, however, the catheter will be too soft or weak. The same occures if holes too large in diameter are used.

In accordance with a preferred embodiment of the invention, a restriction may be arranged along the catheter's length between the proximal holes and the distal holes. The restriction raises the static pressure for the proximal holes which can therefore be made smaller, while reducing the flow speed at the same time.

Holes of different size may thus be arranged along the length of the catheter so that the first holes, as seen from the proximal end, are large and oblong and thereafter diminish in size towards the restriction, while immediately after the restriction the holes may be larger again and diminish in size towards the catheter's distal end. In this way, a substantially equal outflow through all the holes is obtained.

If a restriction is introduced into the catheter, it can be expected that the catheter will have a higher total flow resistance. If, however, the restriction is placed further from the distal end, for instance two-thirds distance from the distal end calculated along the part of the catheter provided with holes, referred to as the vented catheter region, a somewhat reduced total flow resistance is obtained. It is therefore preferred that the restriction is placed at between about 50% and 80% distance from the distal end of the catheter, preferably at about 65% distance, of the vented cahteter region as measured from the distal end.

Additional features, advantages and characteristics of the catheter according to the invention will be apparent from the following detailed description of preferred embodiments of the invention with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of a catheter of the type CD-5001 and depicts a typical example of a catheter according to the state of the art.

Fig. 2 is an enlarged cross-sectional view through the catheter of Fig. 1.

Fig. 3 is an enlarged cross-sectional view similar to Fig. 2, but provided with a tip insert according to the present invention.

Fig. 4 is a schematic diagram of the pressure conditions inside the catheter.

Fig. 5 is a schematic flow diagram at a side hole in the catheter.

Fig. 6 is a cross-sectional view similar to Fig. 3, schematically showing the flow at a restriction in the part of the catheter provided with holes.

Fig. 7 is a cross-sectional view similar to Fig. 3, of one alternative embodiment of the invention.

Fig. 8 is a schematic diagram similar to Fig. 4, of the pressure conditions in a catheter provided with a restriction.

DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 shows a side view of a catheter of known type. The catheter 1 consists of a flexible tube of silicon, which at its proximal end 2 is connected with an arrangement for the supply or removal of dialysis liquid, which is not shown on the drawing.

At the end 2, the catheter is provided with two dacron pads 3, 4. When the catheter is surgically implanted in the peritoneal cavity, the two pads 3 and 4 are at such positions in the insertion tunnel that peritneal fibres may grow attached to the pads 3, 4 and fix the position of the catheter, and thereby prevent infection through the insertion tunnel. The proximal end 2 of the catheter is located outside the skin.

The distal end 5 of the catheter is located inside the peritoneal cavity and is provided with a plurality of holes 6 along its sidewall and a tip opening 7. The catheter is shown in enlarged cross-section in Fig. 2.

In this embodiment, the outer dimater of the catheter d_1 is 5.0 mm and the inner diameter d_2 is 2.7 mm. There may be fifty-six holes with a respective spacing of 3.2 mm and with a hole diameter of about 0.7 mm positioned along the vented catheter region, which may have a length of 90 mm. The holes are

approximately equal in size. These specifications may, however, vary considerably between different catheters and each manufacturer has its own constructions and preferences.

Fig. 3 shows a catheter according to a preferred embodiment of the present invention. The catheter 11 is provided with a plurality of holes 16 along the wall of the catheter defining the vented catheter region 28.
The catheter may comprise an insert 18, which further comprises a restriction 19, as well as an enlarging portion 20, for example in the form of a diffusor with even cross-sectional enlargement 23 (conical) and concludes in a tip opening 17. The inner diameter of the restriction may be 1.5 mm and the diffusor's conicity may be about 8° which, with a length of about 9 mm, results in a final opening diameter of about 2.7 mm, i.e. the same as the original inner diameter of the catheter.

The insert 18 can preferably be dimensioned so that the flow speed through the tip opening is approximately the same as the flow speed through the holes in the catheter's sidewall (see below for more detail).

With the aforementioned dimensions the flow through the tip opening is about 20% of the flow through the side holes, which has shown itself to be a suitable value. By means of this dimensioning, the advantage is obtained that the force which the flow exerts on the catheter tip is not too large and does not cause the catheter to move to too large a degree, i.e. catheter migration is avoided. Additionally, the flow speed through the tip opening is relatively slow, whereby the effect on the peritoneal cavity is minimised.

With certain types of catheter, it is suitable if the flow through the tip opening is less than that which is stated above, for example more than 5 or 10% of the total flow. This is true particularly for catheters with many holes in the sidewall. In

certain cases, it can also be favourable if the tip opening is not present.

In other cases it may be better if a larger part of the total flow passes through the tip opening, such as up to 50% or more of the total flow. Normally however, it is preferred that about 20% to 25% of the total flow passes through the tip opening.

The insert 18 is preferably manufactured of the same material as the rest of the catheter, such as silicon. The whole catheter is preferably made in one single piece in the same manufacturing step. Alternatively, the insert 18 can be manufactured by itself in the same material, or in another material, and be fastened to the catheter tip by means of welding or adhesive, which is of course done in a biocompatible manner.

Alternatively, the insert can be manufactured of a biocompatible plastic material such as polyurethane or polycarbonate.

In a further alternative embodiment of the invention, the insert is made of metal such as titanium or tungsten and thereby has a somewhat larger weight than if it was made of plastics material. This is favourable since the tip of the catheter will thereby automatically be orientated downwardly in the peritoneal cavity, which is generally preferred.

The insert can be embedded in a plastic material which is biocompatible. Other metals can also be used such as silver which also has a certain bacteriostatic function.

In the preferred embodiment of the invention as shown in Fig. 3, the holes 16 are depicted as having different sizes. The object of using holes with different sizes is to obtain approximately the same flow speed out through the various holes.

Fig. 4 shows a schematic diagram of the pressure conditions within the vented catheter region as the liquid moves toward the catheter tip. The pressure in the catheter is made up of a dynamic pressure which corresponds to the movement energy of the fluid (see curve 31) and a static pressure which constitutes the fluid´s pressure against the catheter wall (see curve 32). The sum of the dynamic pressure and the static pressure corresponds to the total pressure (see curve 33). For the sake of simplicity, no account is taken of the hydrostatic pressure.

As shown by curve 31, the dynamic pressure drops towards the catheter tip which is dependent on the fact that the fluid´s flow speed is reduced due to what is given out through the side holes. At the same time, the static pressure rises as shown by curve 32. The total pressure reduces slightly due to, inter alia, the frictional effect against the catheter´s sidewall.

The static pressure at each side hole 16 determines the flow speed through that hole. Thus, the side holes must have a lesser diameter nearer to the tip in order for the same flow speed to be obtained from all the holes, whereby the frictional losses against the sidewall of the hole as well as the losses due to the fluid´s viscosity reduce the outflow speed. A reduction in the outflow speed can probably be obtained alternatively with conical holes where the diameter increases outwardly. Such holes can be manufactured with laser technology or in another way, such as by conical stamps.

In practice, the diameter of the holes does not have to be adapted accurately to the static pressure and it is normally sufficient if two or three different diameters are used. In Fig. 3, the holes 21 are shown with a small diameter close to the catheter tip and holes 22 with a larger diameter further away from the catheter´s tip.

Fig. 5 schematically shows the flow picture for a circular, relatively small hole 21 in the catheter's sidewall. Along the flow lines 24 which lie closest to the sidewall, the fluid particles have a relatively low speed and can therefore, without any great difficulty, be diverted outwardly by the static pressure and pass out through the hole 21. Along the flow lines 25 which are further from the sidewall, the fluid particles are however more difficult to divert and do not manage to be adequately diverted before the hole 21 has been passed. The effective surface area of the hole 21 is therefore reduced. The effective surface area is dependent on the flow speed of the fluid at the hole. In order to obtain the same effective surface area, the hole's cross-sectional area therefore has to be increased further from the catheter tip.

There are thus two reasons for increasing the hole diameter further away from the catheter's tip. It is, however, not possible to increase the hole's diameter too much as the catheter becomes too weak and flexible.

Therefore, in accordance with the present invention, it is proposed to use oblong holes 22, such as are clearly shown in Fig. 3, for the holes which require a larger cross-sectional area. The advantage is thereby obtained that the effective surface area of the hole is used better than with completely circular holes. Additionally, oblong holes affect the integrity of the catheter less so that it does not become too flexible.

It can be difficult to manufacture holes with sufficiently large surface area, despite the measures which are indicated above. It is therefore proposed in accordance with the present invention, that a restriction 26 is arranged approximately in the middle of the vented catheter's region which is provided with holes, as shown in Fig. 3. However, the use of this restriction 26 is optional.

As shown schematically in Fig. 8, the restriction achieves a reduction 35 of the total pressure due to the frictional forces along, and the energy losses across, the restriction, which means that the static pressure is reduced over the restriction since the dynamic pressure is unchanged before and after the restriction (the same flow speed). The static pressure before the restriction is also somewhat higher than without the restriction.

It is therefore possible to use oblong holes 22 furthest away from the tip, followed by small circular holes 21 nearer to the tip and towards the restriction 26. After the restriction oblong holes 22 are first used again and then small circular holes 21 closest to the tip. In this way, approximately the same flow speed is obtained through the various holes.

It can be expected that the total flow resistance for a catheter with such a restriction 26 would be greater than without a restriction. However, it has discoverded that, if the restriction is placed in a certain way, the total flow resistance of the catheter may be minimised. If the restriction is placed about two thirds distance from the tip along the portion of the catheter provided with holes, about the same or even a lower flow resistance is obtained compared to when no restriction is present. According to the invention, a restriction is arranged at a distance of between 50%-80% of the length of the vented catheter region, as measured from the tip. An explanation of this unexpected result may be that the holes before the restriction are used more effectively due to the increased static pressure in this portion.

In a preferred embodiment of the invention forty-eight holes are used, divided in the following way seen from the catheter's tip. First there are ten circular holes with a diameter of 0.8 mm, followed by eighteen oblong holes with the dimensions 0.9 mm x 2.0 mm. Then there is a restriction, followed thereafter by ten

small circular holes with a diameter of 0.8 mm, followed by 10 oblong holes having the dimensions 0.9 mm x 2.0 mm. The distance between the holes is 5 mm.

The restriction is dimensioned so that the flow speed through the various holes is as similar as possible. A suitable dimension is an inner diameter of 2.0 mm with a length of about 4 mm. The size is also dependent on how the inner surface of the restriction looks and on the geometry of the restriction. If the surface is rough or edged, the restriction can be shortened.

As shown in more detail in Fig. 6, the restriction 26 induces eddies 27 in the fluid flow after the restriction. These eddies cause a loss of energy which reduces the total pressure and thus also the static pressure. Moreover, energy losses arise due to frictional forces against the wall of the restriction (increased flow speed) and due to the viscosity.

The pressure conditions before and after the restriction 26 are shown schematically in Fig. 8. The curve 34 for the total pressure shows a steep drop 35 at the restriction. The curve for the dynamic pressure 36 rises sharply at the restriction as shown by a hump 37, but returns thereafter to the same value as before the restriction, since the flow speeds are the same. The curve 38 gives the static pressure, which rises before the restriction but sinks to a lower value after the restriction, approximately corresponding to the starting value, and then rises. The two curve portions of the static pressure before and after the restriction are about the same. In this manner the two parts of the portion provided with holes are used in approximately the same way.

The aforementioned features can be combined in different ways to give the catheter desired characteristics. With catheters which are to be used for extra-sensitive patients, it may be possible to use a long portion provided with holes, which portion has many

holes, and thereby use more than one restriction, such as two or three along the length of the portion having holes.

Referring to Fig. 7 it may be possible to replace the insert 18 with a restriction 42 which is relatively close to the catheter tip, but also sufficiently removed from the tip opening 17 in order that the jet which is obtained from the restriction will have collected into a homogeneous flow.

The restriction 42 is positioned about 20 mm from the tip opening 17, aloowing the flow to collect and reduce in speed before the flow passes through the tip opening 17.

The restrictions 26 and 42 are preferably manufactured of the same material as the rest of the catheter, such as of silicon. The whole catheter is preferably produced in one single piece and in the same manufacturing step. Alternatively, the restrictions may be inserts which are introduced into the catheter and fixed in a suitable way such as by welding or adhesive. Alternatively, the restriction 26 can be mechanically fixed by being provided with projecting pins 43 which fit into holes 21 in the catheter's sidewall. The same materials can be used as for the insert (see above).

The length of, or the tip angle of, the conical portion 20 can be increased so that the orifice has a larger cross-section than the rest of the catheter. Fig. 6 shows an insert 48 with larger tip angle which results in a larger outlet area and lower outflow speed.

Fig. 7 shows further alternative embodiments of the restrictions and holes. A conical restriction 41 is thus shown which consists of a conically diminishing portion, followed by a relatively sharp edge. The fluid's flow speed increases in the conical portion, which results in a large eddy formation after the sharp edge. This eddy formation brings about energy losses which result

in a drop of the total pressure and the static pressure. Additionally, energy losses arise in the form of friction losses against the walls as well as internally in the fluid due to the viscosity.

In order to avoid the effect which is shown in Fig. 5, where only a part of the hole's effective surface area is used, it is proposed that the holes 44 and 45 are arranged at a small angle relative to the normal to the sidewall, such as 10°. Such a slanted arrangement is most noticeable at the start of the portion provided with holes where the flow speed is at its largest.

It can be difficult to reduce the static pressure sufficiently, close to the tip of the catheter. Thus, the small holes at this end can be slightly conically widened, as shown by the hole 46. Since the wall thickness is relatively small, the speed reduction will of course be correspondingly small. This hole can also be arranged in a slanted manner as shown by the hole 47.

The flow conditions for flow of fluid into the peritoneal cavity have been described above. With outward flow, an underpressure is used which sucks the fluid out of the peritoneal cavity. For this, the proximal holes furthest from the tip are used mainly. The fluid passes to a very small extent through the tip opening and the distal holes as well as past the restriction. Only when the proximal holes become blocked due to the fluid at these holes being used up and the catheter sucking on to the peritoneal membrane, does flow occur through the distal holes. This has the beneficial effect that the restrictions do not become blocked by fibres or larger particles which may be present in the fluid in the peritoneal cavity.

The invention has been described above with reference to the embodiments shown in the drawings. The various components and characteristics can however be combined in different ways than have been shown in the drawings and other combinations are included within the scope of the invention. The invention is only limited by the appended claims.

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CLAIMS

1. Catheter, particularly intended to be placed into a body cavity for peritoneal dialysis, comprising a proximal end and a distal end, whereby the catheter includes a vented catheter region (28) intended to be positioned in said cavity and provided with holes (21, 22) along its sidewall, **characterized in that** the vented catheter region has a reduced diameter portion (19).

2. Catheter according to claim 1, **characterized in that** the vented catheter region further comprises a large diameter portion (20) having a diameter larger than the reduced diameter portion (19) and being located more distal than said reduced diameter portion (19).

3. Catheter according to claim 2, **characterized in that** the large diameter portion (20) comprises a conical portion (23) with uniformly increasing diameter, a so-called diffusor.

4. Catheter according to claim 2 or 3, **characterized in that** the vented catheter portion comprises a substantially constant inner diameter and that the large diameter portion comprises a maximum diameter which is substantially equal to said inner diameter.

5. Catheter according to any one of claims 2 - 4, **characterized in that** the catheter further comprises an tip opening (17) at its most distal end, said reduced diameter portion (19) being separated from said tip opening by said large diameter portion (20).

6. Catheter according to any one of claims 1-3, **characterized in that** the distance between the reduced diameter portion (19) and the tip opening (17) is free of said holes (21,22).

7. Catheter according to any one of claims 5 - 6, **characterized in that** the catheter proximal to the vented region comprises a total liquid flow and that the reduced diameter portion (19) and the large diameter portion (20) are dimensioned to allow a partial flow through the tip opening of between 5% - 50% of the total flow, preferably between 20% and 25% of the total flow.

8. Catheter according to any one of claims 3 - 7, **characterized in that** the conical portion (23) has a tip angle of between 3 to 20 degrees, preferably 5 to 15 degrees, and more preferably about 8 to 10 degrees.

9. Catheter according to any one of claims 5 - 8, **characterized in that** the holes (21, 22) and the tip opening (17) have dimensions such that the flow speeds through each hole and through the opening are of about the same magnitude.

10. Catheter according to any one of clams 5 - 9, **characterized in that** the holes (21) nearest to the tip opening (17) have a small cross-sectional area and the holes (22) more proximal from the tip have a diameter which is larger than that of the holes nearest the tip.

11. Catheter according to any one of claims 5 - 10, **characterized in that** the catheter further comprises a longitudinal axis and that the holes (22) with larger cross-sectional area comprise oval cross-section having the longitudinal axis of the oval parallel to said longitudinal axis of the catheter.

12. Catheter according to any one of claims 1 - 11, **characterized in that** it comprises at least one additional reduced diameter portion (26, 41) positioned within the vented region.

13. Catheter according to claim 12, **characterized in that** the cross-sectional areas of the holes increases from a distal reduced diameter portion to the next proximal reduced diameter portion.

14. Catheter according to any one of claims 4 - 13, **characterized in that** the large diameter portion comprises a maximum diameter portion which is larger than said inner diameter.

15. Catheter according to any one of claims 2 - 14, **characterized in that** the large diameter portion located more distal than said reduced diameter portion comprises a diameter substantially equal to a diameter of said vented region.

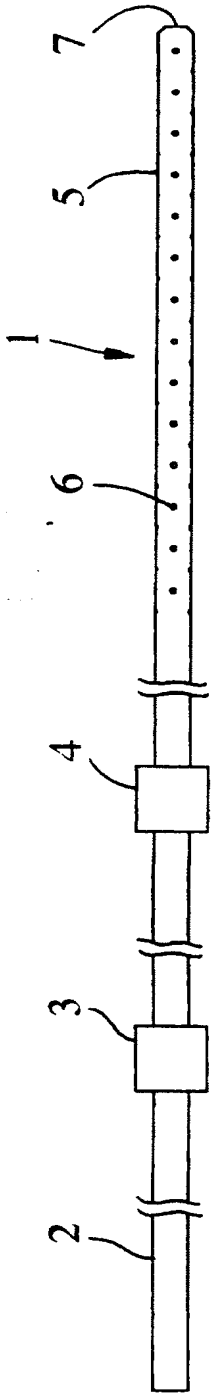

Fig. 1

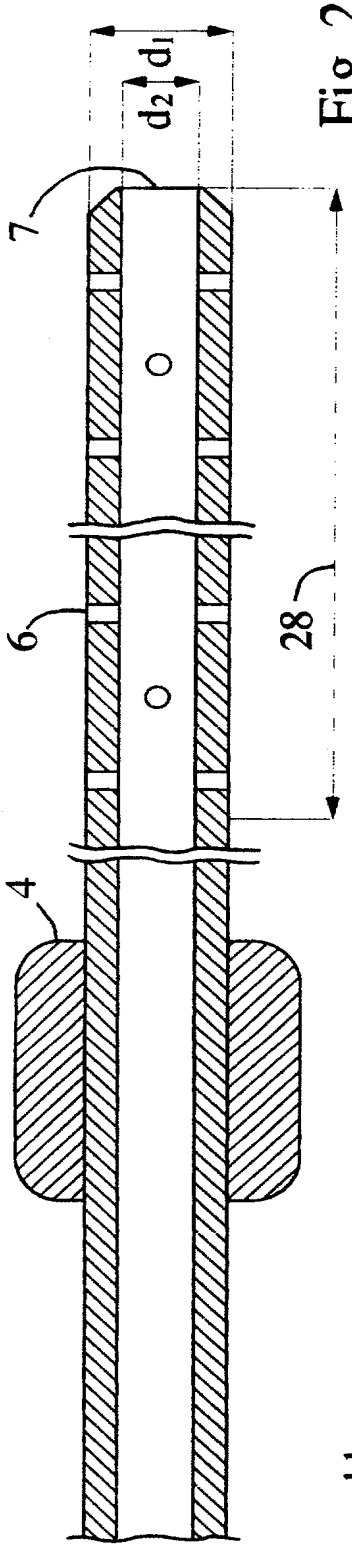

Fig. 2

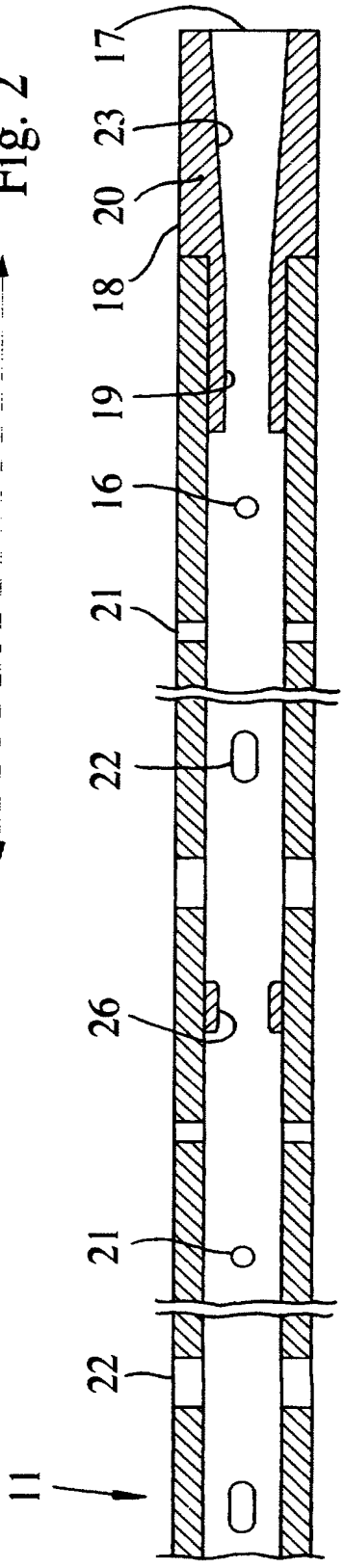

Fig. 3

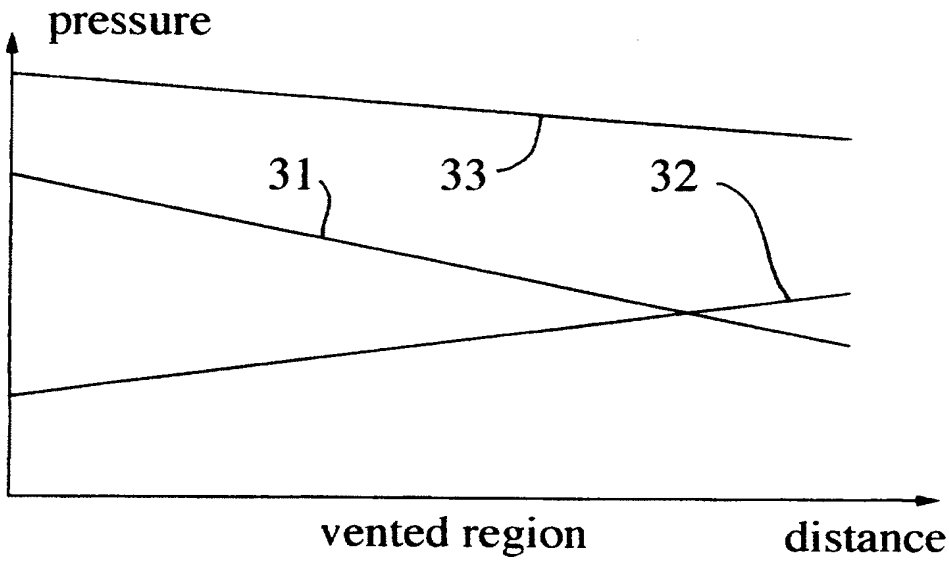

Fig. 4

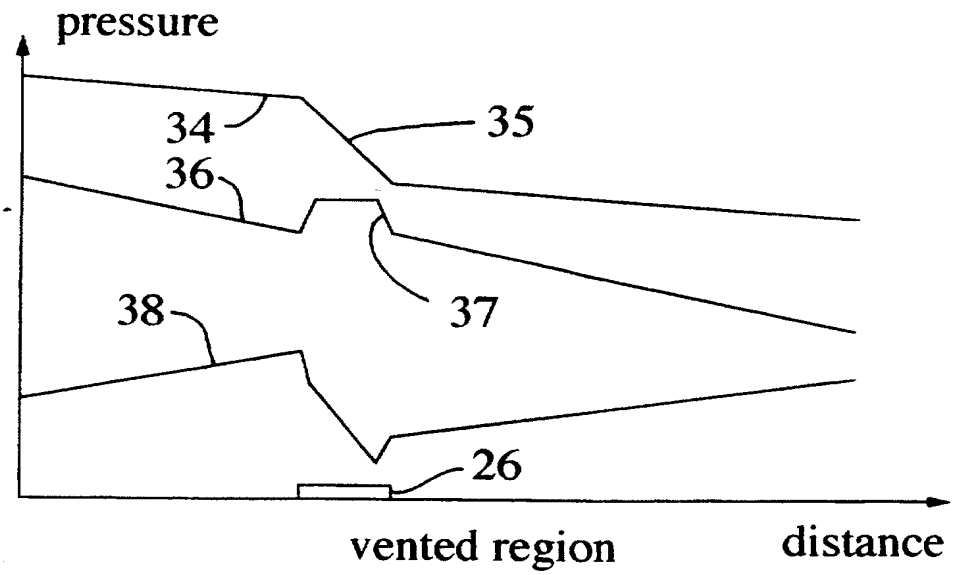

Fig. 8

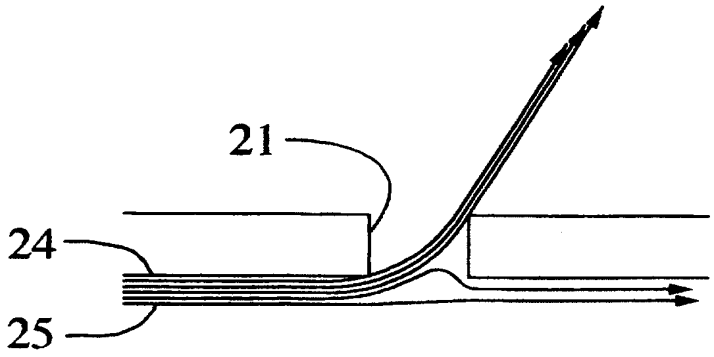

Fig. 5

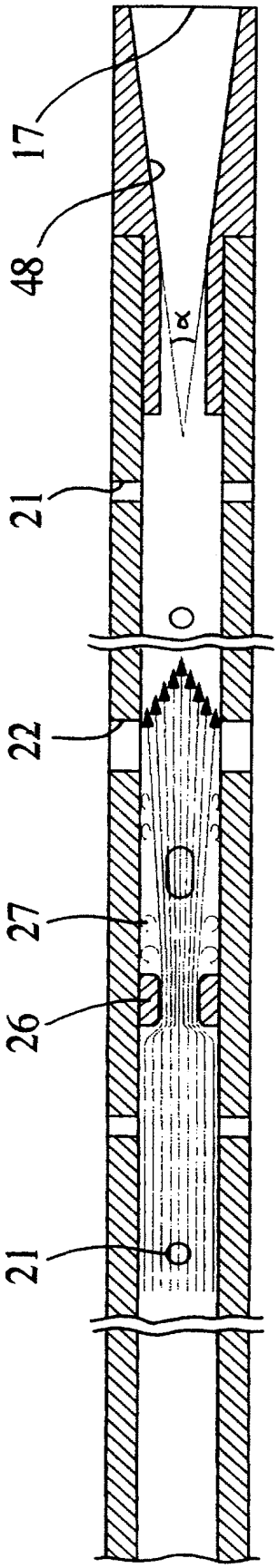

Fig. 6

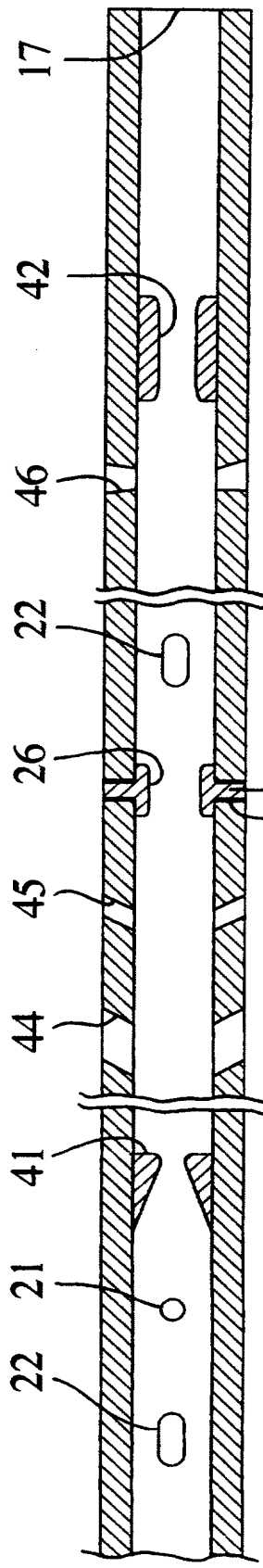

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 96/01280

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 25/14, A61M 1/28
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 8902290 A1 (NEURODYNAMICS, INC.), 23 March 1989 (23.03.89) --	
A -	WO 8606282 A1 (THE CURATORS OF THE UNIVERSITY OF MISSOURI), 6 November 1986 (06.11.86) --	

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 January 1997	28 -01- 1997
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Sune Söderling Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/10/96

International application No.
PCT/SE 96/01280

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 8902290	23/03/89	AU-A- 2425088	17/04/89
		CA-A- 1323537	26/10/93
		CH-A- 678017	31/07/91
		EP-A- 0382753	22/08/90
		JP-T- 3501219	22/03/91
		US-A- 4784638	15/11/88
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WO-A1- 8606282	06/11/86	CA-A- 1269004	15/05/90
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		DE-D,T- 3689025	27/01/94
		EP-A,B- 0220288	06/05/87
		JP-T- 62502948	26/11/87
		US-A- 4687471	18/08/87
		US-A,B- 4772269	20/09/88